

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.



(19) Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11) Publication number:

0 551 574 A1

(12)

## EUROPEAN PATENT APPLICATION

(21) Application number: 92117694.7

(51) Int. Cl.5: A61F 2/36, A61F 2/28,  
A61L 27/00

(22) Date of filing: 16.10.92

(30) Priority: 13.01.92 US 819722

(71) Applicant: Bristol-Myers Company  
345 Park Avenue  
New York New York 10154(US)

(43) Date of publication of application:  
21.07.93 Bulletin 93/29

(72) Inventor: Chu, Helen S.  
2204 Cambridge Drive  
Goshen, IN 46526(US)  
Inventor: Devanathan, Thirumalai N.C.  
265-B Ross Avenue  
Warsaw, IN 46580(US)

(84) Designated Contracting States:  
DE FR GB IT

(74) Representative: Eisenführ, Speiser & Partner  
Martinistraße 24  
W-2800 Bremen 1 (DE)

(54) Composite implant with metallic braid.

(57) A bone implant includes two non-metallic layers (2,4) and an inner layer (3) composed of metallic wire. The metallic wire enhances the attachment of the various layers and makes the implant visible on a radiogram.

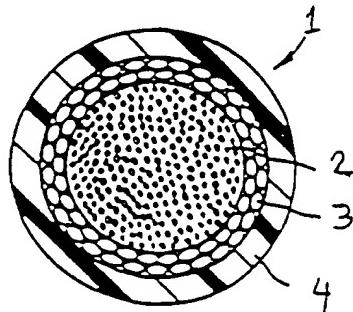


FIG. 2

## BACKGROUND OF THE INVENTION

The invention of this disclosure relates to composite bone implants.

There have been many attempts to improve bone implants by constructing them of composite materials. U.S. Patent 4,714,467 teaches the use of a composite hip stem with a support collar, a core composed of longitudinal carbon fibers, a braided carbon fiber sheath surrounding the core and a polymer matrix impregnating both sets of fibers. The outer surface is then treated to expose some of the fibers to the bony environment. U.S. Patent 4,902,297 teaches a composite implant prosthesis adapted for efficient mass production comprising a composite carbon fiber core, a braided composite carbon fiber casing over the core and an outer polymer casing defining the desired shape of the implant. UK Patent Application GB 2 216 425 A teaches a bone implant having a core of longitudinally extending fibers, a braided fiber sheath, a polymer skin and a pair of porous fiber metal pads secured to the skin. U.S. Patent 4,750,905 teaches a prosthesis with a composite carbon fiber core, a braided carbon fiber sheath over the core and a polymer skin fused to the core and sheath to define the outer prosthesis geometry. This patent discusses the difficulties in bonding a layered implant. This difficulty in forming a bond may occur during the molding process in which a molten polymer is injected around the relatively cool core and sheath. Because of this temperature difference, the interface between the hot and cold layers cools quickly without efficient fusing of the layers. Improved bonding may be achieved by heating the core prior to molding. However, heating the core, especially a composite one, usually results in distortion of the core and a loss of core compaction. Another proposed solution has been to repeatedly dip the core in a polymer and solvent solution, thereby depositing an increasingly thicker polymer layer. This process is laborious at best. In addition to bonding difficulties, prior devices have had the disadvantage of being difficult or impossible to see on a radiogram.

## SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a composite bone implant forming a strong initial bond between its various layers. Another object of the invention is to provide a construction that can be further processed to increase the amount of bonding between its layers. It is a further object of the invention to provide a bone implant that can be readily seen on a radiogram. These and other objectives are achieved by a bone implant comprising a first non-metallic layer, a met-

al fiber inner layer and a second non-metallic layer.

## BRIEF DESCRIPTION OF THE DRAWINGS

5 The before mentioned objects and advantages of the present invention are apparent from the following detailed description and the drawings wherein:

10 FIG. 1 is a side view of a femoral hip prosthesis according to the present invention.

15 FIG. 2 is a cross sectional view taken along line 2-2 of FIG. 1.

## DETAILED DESCRIPTION OF THE INVENTION

15 Referring to FIGS. 1 and 2, a preferred embodiment of a femoral hip prosthesis 1 is depicted having a longitudinally oriented composite fiber core first layer 2, a braided metallic sheath inner layer 3 over the core and an outer skin second layer 4. Such a prosthesis can be made by several methods. An exemplary method is disclosed in U.S. Patent 4,902,297 in which a core is formed by drawing polymer impregnated carbon fibers through a die. A sheath of polymer impregnated carbon fibers is then braided over the core. Finally, the core and sheath are placed into an injection molding die and the polymer skin is molded over the core and sheath. It is advantageous to pre-heat the core and sheath prior to the molding step. However, the pre-heat temperature is limited to be below the temperature at which the core will deform or lose compaction or delaminate. For an implant according to the present invention, the braided sheath comprises metal wires. The advantage of using metal wires lies in the mechanical interlock of the polymer with the wire and the further ability of certain polymers to adhere more readily to a wire sheath than to a carbon fiber sheath, thereby imparting enhanced bonding to the layers. The implant is formed so that all of the fibers of the core and sheath are encapsulated and only the polymer skin is exposed to the environment. Polymers of the polyaryletherketone (PAEK) family have the desired adherence to metal as well as appropriate biocompatibility for use as an implant. The metal wires can be made of any suitable metal such as stainless steel or titanium alloys. Also, the metal wire layer may be formed by many processes including braiding, winding, weaving or simply matting the fibers together.

50 In addition to this initially improved bond due to the polymer adhering to the metal, the bond can be further enhanced by induction heating. When an object containing metal is placed in an induction heater, the metal is heated while the non-metallic components remain relatively cool. In induction heater, the metal sheath is heated which in turn

heats the polymer at the interface between layers resulting in more complete bonding between layers. Such localized heating is advantageous because it does not result in deformation of the implant as would occur from gross heating of the implant, but it does provide to the interface between layers the extended time at an elevated temperature needed to form an enhanced interlayer bond.

Finally, apart from improved bond strength, the metal sheath serves to block X-rays so that the implant is visible on a radiogram. This is desirable so that a surgeon may verify implant placement post surgically.

While the foregoing has described a preferred embodiment of the present invention, variations in design and construction are possible. An implant configuration with first and second non-metallic layers and a metallic wire inner layer between them is within the scope of this invention; whether it be for a hip joint, knee joint, fracture fixation plate or other application.

## Claims

1. A bone implant, comprising:  
a first non-metallic layer;  
a second non-metallic layer; and  
a metallic fiber inner layer disposed between the first and second layers, the inner layer and the second layer being securely joined.
2. The implant of claim 1 wherein a bond is formed between two of the layers by inductively heating the inner layer.
3. The implant of claim 1 wherein the metallic fiber inner layer comprises a braided sheath surrounding the first non-metallic layer.
4. The implant of claim 1 wherein the first non-metallic layer comprises a thermoplastic.
5. The implant of claim 3 wherein the thermoplastic includes a member of the polyaryletherketone family of polymers.
6. The implant of claim 3 wherein the first non-metallic layer further comprises fibers.
7. The implant of claim 6 wherein the first non-metallic layer includes carbon fibers.
8. A femoral hip prosthesis, comprising:  
a non-metallic core layer;  
a metallic fiber sheath layer over the core;  
and

5 a non-metallic skin layer formed over the core and sheath.

9. The femoral hip prosthesis of claim 8 wherein a bond is formed between two of the layers by inductively heating the inner layer.
10. The femoral hip prosthesis of claim 8 wherein the metallic fiber sheath is braided and surrounds the non-metallic core layer.
11. The femoral hip prosthesis of claim 8 wherein the core comprises a thermoplastic and fibers.
12. The femoral hip prosthesis of claim 11 wherein the core includes a member of the polyaryletherketone family of thermoplastics and the fibers include carbon.
13. The implant of claim 12 wherein the skin includes a member of the polyaryletherketone family of thermoplastics.
14. A femoral hip prosthesis comprising:  
a core including carbon fibers impregnated with a thermoplastic polymer;  
a braided metallic fiber sheath enclosing the core; and  
a skin layer, including a thermoplastic polymer, formed over the core and sheath such that none of the fibers of the core or sheath are exposed.

35

40

45

50

55

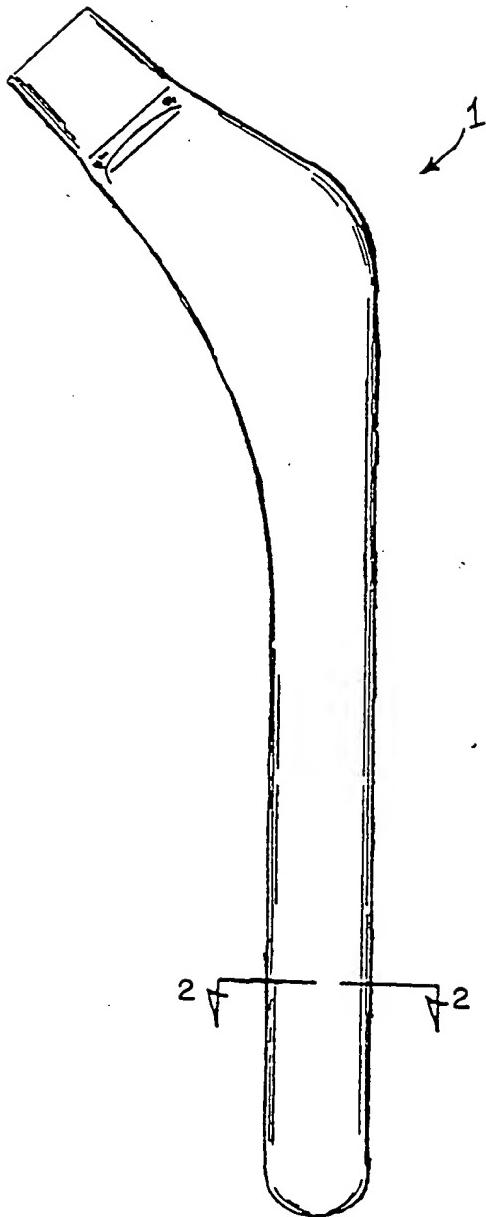


FIG. 1

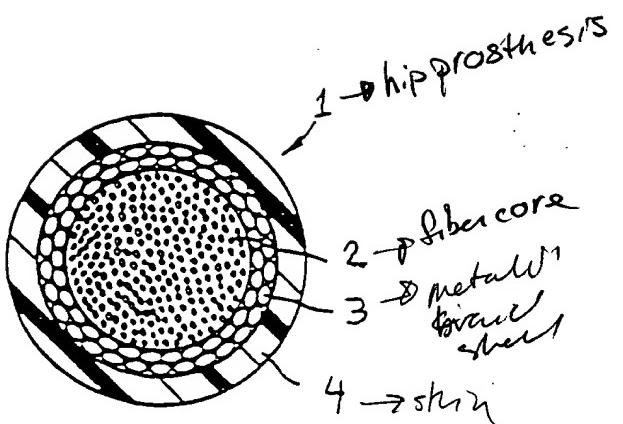


FIG. 2



European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number

EP 92 11 7694

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A,D	GB-A-2 216 425 (BRISTOL-MYERS COMPANY) * page 7, line 3 - page 8, line 13; figures * ---	1-14	A61F2/36 A61F2/28 A61L27/00
A	WO-A-9 000 374 (LABOR FÜR EXPERIMENTELLE CHIRURGIE) * page 3, line 21 - line 23; figures * ---	1,8,14	
A	FR-A-2 105 998 (GULF OIL CORPORATION) * claims 1,4; figures * ---	1,8,14	
A	US-A-3 662 405 (BORTZ ET AL.) * column 2, line 36 - line 54 * * column 3, line 61 - line 65; figures * -----	1,8,14	
TECHNICAL FIELDS SEARCHED (Int. Cl.5)			
A61F A61L A61B			
The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	25 FEBRUARY 1993	GODOT T.	
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone	T : theory or principle underlying the invention		
Y : particularly relevant if combined with another document of the same category	E : earlier patent document, but published on, or after the filing date		
A : technological background	D : document cited in the application		
O : non-written disclosure	L : document cited for other reasons		
P : intermediate document	& : member of the same patent family, corresponding document		